

Dkt No. PP00362.102
USSN: 09/674,183
PATENT

REMARKS

Introductory Comments:

Claims 1-8, 10-17, 19, 21 and 23 were examined in the Office Action under reply and stand variously rejected under 35 U.S.C. §112, second paragraph (claims 1-17, 19, 21 and 23); and (2) 35 U.S.C. §102 (claims 1-4, 7, 8, 10-17, 19, 21 and 23). These rejections are respectfully traversed as discussed more fully below. Applicants note that neither of claims 5 or 6 was subject to an art rejection.

Formal drawings with the changes requested by the Examiner and draftsperson are being provided under separate cover.

Overview of the Above Amendments:

The specification has been amended to correct obvious typographical errors, as well as to insert subparts for the figures and identify trademarks, as requested by the Examiner.

Claims 1-3, 7, 9, 17-20 and 22-32 have been cancelled and claims 4-6, 8, 11, 13-16 and 21 amended to recite the invention with greater particularity. New claims 33-44 have been added.

In particular, claim 4 has been rewritten in independent format and now recites that the carrier protein comprises at least five different CD4+ T cell epitopes selected from the specified group of epitopes and that at least one of the CD4+ T cell epitopes is an HBVnc, HA, HbsAg, MT or hsp70 CD4+ T cell epitope. Minor wording changes have been made to the claims and improper multiple dependencies eliminated, to conform to U.S. practice. New claims 33-44 pertain to embodiments previously present in the multiple dependent claims.

Cancellation of claims 1-3, 7, 9, 17-10 and 22-32, and amendment of claims 4-6, 8, 11, 13-16 and 21 is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications hereof containing the canceled or unamended claims.

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Rejections Under 35 U.S.C. §112, Second Paragraph:

Claims 1-17, 19, 21 and 23 were rejected under 35 U.S.C. §112, second paragraph, as indefinite. The Examiner contends that the term "derived" in claims 1, 2 and 13 is unclear. This term no longer appears in the claims. Hence, this basis for rejection has been overcome.

Claims 19 and 23 were rejected based on the use of the phrase "The carrier protein..." These claims have been cancelled, rendering this rejection moot.

Claims 2-8 were rejected as lacking proper antecedence. The Examiner suggests replacing the term "the CD4+ epitopes" with "the CD4+ T cell epitopes." Applicants have so done. Thus, this basis for rejection has also been overcome.

Claims 4-7 were rejected as indefinite for use of the abbreviations "MT" and "HA." Applicants direct the Examiner's attention to Table I, page 36, of the specification where the MT and HA epitopes are defined. Accordingly, the terms as used in the claims are sufficiently clear and withdrawal of this basis for rejection is respectfully requested.

Claims 11, 14 and 15 were rejected as indefinite as lacking an article before polysaccharide (claim 11) and protein (claims 14 and 15). Claim 11 has been amended to recite "a polysaccharide" and claims 14 and 15 now recite that the polysaccharide is conjugated to "the carrier protein." Thus, these bases for rejection have been overcome.

Claim 16 was rejected as indefinite based on the use of the term "unit" in the claim. This term has been eliminated. Hence, this basis for rejection has also been overcome.

Claim 21 was rejected as indefinite based on the recitation "a carrier protein..." The claim has been amended to recite "the carrier protein..." as suggested by the Examiner. Therefore, this basis for rejection has also been overcome.

Withdrawal of the bases for rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

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Rejections Under 35 U.S.C. §102:

Claims 1-4, 8, 10-12, 14, 16, 17, 19, 21 and 23 were rejected under 35 U.S.C. §102(b) as anticipated by Peeters et al., *Infect. Immun.* (1992) 60:1826-1833 ("Peeters") as evidenced by Falugi et al., *Eur. J. Immunol.* (2001) 31:3816-3824 ("Falugi"). Additionally, claims 1-4, 8, 10, 11, 13-17, 19 and 21 were rejected under 35 U.S.C. §102(b) as anticipated by Jennings et al., In *Seminars in Infectious Disease* (1982) Chapter 34, pp247-253 ("Jennings") as evidenced by Falugi. Finally, claims 1 and 7 were rejected under 35 U.S.C. §102(b) as anticipated by International Publication No. WO 86/05790 to Nussenzweig et al. ("Nussenzweig") as evidenced by Falugi. Applicants note that neither of claims 5 or 6 were subject to the above art rejections.

Peeters, Jennings and Nussenzweig are each cited for teaching the protein carrier TT conjugated to a Hib polysaccharide (Peeters), a polysaccharide of *N. meningitidis* (Jennings) and a PfCs (Nussenzweig). The Office states that Falugi shows that TT contains at least five CD4+ T cell epitopes, P23TT, P32TT, P21TT, P30TT and P2TT. However, applicants submit that neither of Peeters, Jennings and Nussenzweig anticipate the claimed invention.

The law is clear that in order to anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986). *Atlas Powder Co. v. E. I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984). Moreover, the single source must disclose all of the claimed elements "arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Finally, the law requires identity between the claimed invention and the prior art disclosure. *Kalman v. Kimberly-Clark Corp.* 713 F.2d 760, 771, 218 USPQ 2d 781, 789 (Fed. Cir. 1983, cert. denied, 465 U.S. 1026 (1984)).

None of Peeters, Jennings or Nussenzweig teach or suggest a carrier protein comprising at least five different CD4+ T cell epitopes selected from the group of

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epitopes specified in the claims, wherein at least one of the epitopes is a HBVnc, HA, HbsAg, MT or hsp70 CD4+ T cell epitope. Since the cited references do not teach each and every element of the claims, they cannot anticipate the present invention. Thus, withdrawal of the above bases for rejection under 35 U.S.C. §102(b) is respectfully requested.

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CONCLUSION

Applicant respectfully submits that the claims define a patentable invention. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Please direct all further written communications in this application to:

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Respectfully submitted,

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